OLYMPUS

K081561

JUL 28 2008

510(k) SUMMARY

OSferion D

May 30, 2008

1 General Information

■ Owner/Operator:	OLYMPUS TERUMO BIOMATERIALS CORP. 34-3 Hirai, Hinode-machi, Nishitama-gun, Tokyo 190-0182, Japan Establishment Registration No: 3006617492
■ Official Correspondent:	Stacy Abbatiello Kluesner, RAC Regulatory Affairs & Quality Assurance Olympus America Inc. 3500 Corporate Parkway PO Box 610 Center Valley PA18034-0610 Phone: (484) 896-5405 Facsimile: (484) 896-7128 Email: Stacy.Kluesner@olympus.com Establishment Registration No: 2429304
■ Manufacturer: (Sterilization site)	OLYMPUS TERUMO BIOMATERIALS CORP. Hinode Factory 34-3 Hirai, Hinode-machi, Nishitama-gun, Tokyo 190-0182. Japan Establishment Registration No: 3006617492

2 Device Identification

■ **Device Trade Name:**	OSferion D
■ **Common Name:**	Bone void filler, Synthetic
■ **Regulation Number:**	21 CFR 872.3930
■ **Regulation Name:**	Bone grafting material, synthetic
■ **Regulatory Class:**	II
■ **Product Code:**	LYC
■ **Classification panel**	Dental

3 Predicate Device/Reference Device Information

	Predicate Device		Reference Device	
Device Name:	Cerasorb® M DENTAL	BioResorb® Macro Pore	OSferion	Vitoss® Scaffold Synthetic Cancellous Bone Void Filler
Common Name:	Bone Void Filler, Synthetic	Bone Void Filler, Synthetic	Bone void filler	Bone void filler
Manufacturer:	Curasan AG	Oraltronics Dental Implant Technology GmbH	OLYMPUS TERUMO BIOMATERIALS CORP.	ORTHOVITA, INC.
510(k) No.	K051443	K050260	K080065	K032409

4 Device Description

OSferion D is a white porous material composed of Beta-tricalcium phosphate(β-TCP). It is intended to fill, augment, or reconstruct periodontal or bony defects of the oral and maxillofacial region. The ceramic material complied with US standard specification ASTM F 1088-04.

The OSferion D product range consists of two product types with porosities of 75% and 60% and of three granule sizes (G0:0.15~0.8mm,G1:0.5~1.5mm,G2:1.0~3.0mm).

5 Indications for Use

It is intended to fill, augment, or reconstructive periodontal or bony defects of the oral and maxillofacial region.

- Augmentation or reconstructive treatment of the alveolar ridge.
- Filling of infrabony periodontal defects.
- Filling of defects after root resection, apicoectomy, and cystectomy.
- Filling of extraction sockets to enhance preservation of the alveolar ridge.
- Elevation of the maxillary sinus floor.
- Filling of periodontal defects in conjunction with products intended for Guided Tissue Regeneration (GTR) and Guided Bone Regeneration (GBR).
- Filling of peri-implant defects in conjunction with products intended for Guided Bone Regeneration(GBR).

6 Comparison of Technological Characteristics

OSferion D is substantially equivalent to the predicate devices in indication for use, and in specifications of the material.

Information provided in this submission supports the safety and effectiveness of OSferion D compared to the predicate device.

7 Conclusion

When compared to the predicate device, this subject device "OSferion D" does not incorporate any significant changes in intended use, instruction for use, material, or design that could effect the safety or effectiveness of the device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Olympus Terumo Biomaterials Corporation
C/O Ms. Stacy Abbatiello Kluesner, RAC
Regulatory Affairs & Quality Assurance
Olympus America, Incorporated
3500 Corporate Parkway
P.O. Box 610
Center Valley, Pennsylvania 18034-0610

JUL 2 8 2008

Re: K081561
Trade/Device Name: OSferion D
Regulation Number: 872.3930
Regulation Name: Bone Grafting Material
Regulatory Class: II
Product Code: LYC
Dated: June 2, 2008
Received: June 13, 2008

Dear Ms. Kluesner:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K081561

Indications for Use Statement

510(k) Number (if known) :

Device Name : OSferion D

Indications for Use :

It is intended to fill, augment, or reconstruct periodontal or bony defects of the oral and maxillofacial region.

- Augmentation or reconstructive treatment of the alveolar ridge.
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Prescription Use ✓ AND/OR Over-The-Counter Use_____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K081561